Coherus BioSciences Reports Fourth Quarter and Full Year 2016 Corporate Highlights and Financial Results

Mar 13, 2017

REDWOOD CITY, Calif., March 13, 2017 (GLOBE NEWSWIRE) -- Coherus BioSciences, Inc. (Nasdaq:CHRS), today reviewed corporate events and reported financial results for the fourth quarter and full year 2016.

Corporate Highlights for the Fourth Quarter 2016 Include:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim (Neulasta®) biosimilar candidate)
  - Announced that the U.S. FDA has accepted the filing of 351(k) Biologics License Application (BLA) for CHS-1701. The first FDA submission and acceptance for Coherus.
  - Announced acceptance of Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for CHS-1701. This is the first EMA submission and acceptance for Coherus.

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab (Humira®) biosimilar candidate)
  - Received decision from the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office denying institution of petition for Inter Partes Review (IPR) of AbbVie's U.S. Patent 9,114,166 (the "'166 Patent") related to AbbVie's HUMIRA (adalimumab) formulation.
- CHS-0214 (etanercept (Enbrel®) biosimilar candidate)
  - Announced results from two pharmacokinetic (PK) studies involving CHS-0214. The CHS-0214-06 trial compared CHS-0214 vs. European Union (EU) Enbrel and achieved the primary PK BE endpoint, as the 90% confidence intervals for the geometric mean ratio for the two groups was within 80% to 125% for all PK parameters. The CHS-0214-07 trial provided additional relative bioavailability data for CHS-0214.

Financial Highlights for the Fourth Quarter 2016 include:

- On October 28, 2016, Coherus entered into a Sales Agreement with Cowen and Company, LLC to sell shares of the Company's common stock with aggregate gross sales proceeds of up to $100,000,000, from time to time, through an "at the market" equity offering program under which Cowen will act as sales agent. During the fourth quarter of 2016 and in January 2017, Coherus issued 2.2 million shares and raised $60.8 million in gross proceeds under this program at an average price per share of $28.10.

Fourth Quarter and Full Year 2016 Financial Results:

- **Total revenue** for the fourth quarter of 2016 was $844 thousand, as compared to $10.2 million in the fourth quarter of 2015. Total revenue for the fiscal year 2016 was $190.1 million, as compared to $30.0 million in 2015. The increase over the same period in 2015 was due to increased recognition of collaboration revenue as a result of regaining the full development and commercial rights for CHS-0214 from Shire in Europe, Canada, Brazil, the Middle East and certain other territories.

- **Research and development (R&D)** expenses for the fourth quarter of 2016 were $59.0 million compared to $51.4 million for the same period in 2015. R&D expenses for the fiscal year 2016 were $254.4 million, as compared to $213.1 million for the same period in 2015. The increase in R&D expenses in the fourth quarter over the same period in 2015 was mainly due to analytical studies for early stage programs and CHS-0214 programs, on-going CHS-1420 PK and Phase 3 trials, offset by completion of the CHS-1701 BLA-enabling and CHS-0214 Phase 3 clinical program. The increase in R&D expenses in the fiscal year ended 2016 over the same period in 2015 was mainly attributable to proceeding with clinical activities associated with a Phase 3 clinical study in psoriasis for CHS-1420, advances in other product candidates, and hiring additional personnel to support both late-development and early-stage activities, partially offset by a decrease in costs related to BLA-enabling studies for CHS-1701 and a decrease in costs associated with the CHS-0214 Phase 3 trials that were completed in the first half of 2016.

- **General and administrative (G&A)** expenses for the fourth quarter of 2016 were $15.3 million, compared to $11.0 million for the same period in 2015. G&A expenses for the fiscal year 2016 were $51.6 million, as compared to $36.0 million for the same period in 2015. Changes in G&A expenses were mainly attributable to hiring employees to support pre-commercial and accounting activities, costs associated with stock options granted since the third quarter of 2015 and legal fees to support the intellectual property strategy.

- **Net loss** attributable to Coherus for the fourth quarter of 2016 was ($75.9) million, or ($1.71) per share, compared to a net

loss of ($52.4) million, or ($1.35) per share, for the same period in 2015. Net loss attributable to Coherus for 2016 was ($127.3) million, or ($3.04) per share, compared to a net loss of ($223.3) million, or ($6.01) per share, for 2015.

- **Cash and cash equivalents** totaled $124.9 million as of December 31, 2016, compared to $159.7 million as of September 30, 2016. Coherus raised an additional $120.3 million in net proceeds from a follow-on equity offering in February and March 2017.

2017 Guidance:
Oncology therapeutic franchise:

- CHS-1701 (pegfilgrastim biosimilar)
  - U.S. marketing approval, anticipated on the BSUFA date of June 9, 2017.
  - European Marketing approval anticipated in the fourth quarter of 2017.
  - Continue commercial partnering discussions for certain ex-U.S. territories, targeting agreement in place in the first half of 2017.

Immunology (anti-TNF) therapeutic franchise:

- CHS-1420 (adalimumab biosimilar)
  - Anticipate a 351(k) BLA submission in the U.S. in the second quarter of 2017.
  - Anticipate a decision from the Patent Trial and Appeal Board of the U.S. Patent and Trademark office on the Inter Partes Review of AbbVie's U.S. Patent 8,889,135 ("the '135 Patent") by May 17, 2017.
  - Continue to advance intellectual property strategies, supporting potential 2018 launch.
  - Initiate a PK study on formulation not impacted by AbbVie US Patent 9,114,166 ('166) in the second-half of 2017, if the '135 Patent is invalidated by the Patent Trial and Appeal Board.
  - Institution decision on four petitions for Inter Partes Review (IPR) of AbbVie's U.S. Patent 9,085,619 in the third quarter of 2017.
- CHS-0214 (etanercept biosimilar)
  - Anticipate filing of Marketing Authorization Application (MAA) in the second half of 2017.
- Partnering discussions for the immunology (anti-TNF) therapeutic franchise are underway, targeting agreement in place in the first half of 2017, subject to a favorable '135 IPR decision.

Other:

- Complete additional animal studies on CHS-131 to further validate its mechanism of action, pursuant to a licensing agreement in the second half of 2017.
- Management anticipates prioritizing use of cash towards CHS-1701 commercialization activities.

Conference Call Information
When: Monday, March 13, 2017 at 4:30 p.m. ET
Dial-in: (844) 452-6826 (toll free) or (765) 507-2587 (International)
Conference ID: 66529524
Webcast: http://investors.coherus.com
Please join the conference call at least 10 minutes early to register. The webcast will be archived on the Coherus website.

About Coherus BioSciences, Inc.
Coherus is a leading pure-play, global biosimilar company that develops and commercializes high-quality therapeutics for major regulated markets. Biosimilars are intended for use in place of existing, branded biologics to treat a range of chronic and often life-threatening diseases, with the potential to reduce costs and expand patient access. Composed of a team of proven industry veterans with world-class expertise in process science, analytical characterization, protein production, sales & marketing and clinical-regulatory development, Coherus is positioned as a leader in the global biosimilar marketplace. Coherus is advancing three late-stage clinical products towards commercialization, CHS-1701 (pegfilgrastim biosimilar), CHS-0214 (etanercept biosimilar) and CHS-1420 (adalimumab biosimilar), as well as developing a robust pipeline of future products in four therapeutic areas, oncology, immunology (anti-TNF), ophthalmology and multiple sclerosis. For additional information, please visit www.coherus.com.

Forward-Looking Statements
Except for the historical information contained herein, the matters set forth in this press release, including statements regarding Coherus' plans, potential opportunities, expectations, projections, goals, objectives, milestones, strategies, product pipeline, clinical studies, product development, release of data and the potential benefits of its products under development are forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including Coherus' ability to complete a partnering agreement and receive MAA acceptance for CHS-1701, receive MAA acceptance for CHS-0214, initiate a bioavailability study for CHS-0214 and receive BLA acceptance for CHS-1420, complete a partnering agreement for its immunology (anti-TNF) therapeutic franchise, to complete additional studies for and partner CHS-131, to prioritize its use of cash towards CHS-1701 commercialization activities, and to successfully defend against the trade secret and related allegations made by Amgen in the lawsuit filed against Coherus and other parties with respect to CHS-1701 and to be able to launch that product on a timely basis assuming approval of our New Drug Application by the U.S. Food and Drug Administration. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the clinical drug development process, including the regulatory approval process, the timing of our regulatory filings and other matters that could affect the availability or commercial potential of our biosimilar drug candidates, as well as possible patent litigation. Coherus undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Coherus' business in general, see Coherus' Annual Report on Form 10-K for the year ended December 31, 2016, filed with the Securities and Exchange Commission on March 13, 2017 and its future periodic reports to be filed with the Securities and Exchange Commission.

Coherus BioSciences, Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2016	2015	2016	2015
	(unaudited)			
Revenue:				
Collaboration and license revenue	$ 214	$ 10,198	$ 189,476	$ 30,041
Other revenue	630	—	630	—
Total revenue	844	10,198	190,106	30,041
Operating expenses:				
Research and development	59,010	51,433	254,440	213,062
General and administrative	15,294	10,972	51,597	36,046
Total operating expenses	74,304	62,405	306,037	249,108
Loss from operations	(73,460)	(52,207)	(115,931)	(219,067)
Interest expense	(2,369)	—	(7,980)	(33)
Other expense, net	(115)	(373)	(3,877)	(4,838)
Net loss	(75,944)	(52,580)	(127,788)	(223,938)
Net loss attributable to non-controlling interest	23	189	451	678
Net loss attributable to Coherus	$ (75,921)	$ (52,391)	$ (127,337)	$ (223,260)
Net loss per share attributable to Coherus, basic and diluted	$ (1.71)	$ (1.35)	$ (3.04)	$ (6.01)
Weighted-average number of shares used in computing net loss per share attributable to Coherus, basic and diluted	44,341,121	38,935,832	41,912,300	37,122,008

Coherus BioSciences, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	December 31, 2016	December 31, 2015
Assets		
Cash and cash equivalents	$ 124,947	$ 158,226
Other assets	53,538	54,158
Total assets	$ 178,485	$ 212,384
Liabilities and Stockholders' Equity (deficit)		
Deferred revenue	1,561	94,959
Convertible notes	75,192	—
Convertible notes-related parties	25,064	—
Other liabilities	57,314	124,354
Total stockholders' equity (deficit)	19,354	(6,929)
Total liabilities and stockholders' equity (deficit)	$ 178,485	$ 212,384

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